K 000328

MAY - 9 2000

510 (k) Summary

This summary regarding 510(k) safety and effectiveness and being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

807.92(a)(1) Submitter's (and Contact) Name, Address, Telephone No., Summary Date

Cathy Chenetski
Director, Regulatory Affairs
Medex
6250 Shier Rings Road
Dublin, OH 43016
(614) 791-5412

April 25, 2000

807.92(a)(2) Device Name (Including Trade Name), Common Name, Classification Name

Classification Name:	Syringe Infusion Pump (80 FRN)
Common/Usual Name:	Syringe Infusion Pump
Trade/Propriety Name:	Protégé
Part Number:	Medex 3000 Series MRI Syringe Infusion Pump

807.92(a)(3) Legally Marketed Predicate Device to Which Equivalence is Claimed

The Medex 3000 Series MRI Syringe Infusion Pump, is identical to the Medex 3000 Series Syringe Infusion Pump (K982640). This modification consists of changes to the marketing claims not the device. At the time of the original submission, no testing had been completed relative to use in the MR environment. As a result, no claims were made relative to the device being acceptable for use in the MR environment. Medex has since completed that testing and intends to modify the device claims accordingly.

807.92(a)(4) Description of the Premarket Notification Device and 807.92 (a) (5) Intended Use

Although there have been no changes to the device, the device description is included herein for convenience.

The Medex 3000 Series MRI Syringe Infusion Pump is a software driven, microprocessor controlled, electromechanical system that contains within its case: user interface, power supply, motor, pumping mechanism, and electronic circuits required to effect the controlled infusion of fluids through a syringe and a sterile administration set. The pump operates by controlled displacement of the syringe plunger.

The Medex 3000 Series MRI Syringe Infusion Pump's intended use will remain unchanged with the modified claims. The device will now be marketed as MRI Compatible with MR Systems of 1.5 Tesla and radiofrequency transmission and reception at 64 MHz. The intended use is as follows:

The Medex 3000 Series MRI Syringe Infusion Pump is intended for use in the administration of fluids requiring precisely controlled infusion rates including blood and blood products, lipids, drugs and other therapeutic fluids via arterial, epidural, intravenous, spinal and subcutaneous routes. The pumps are indicated for use in continuous, volume/time, body weight, custom dilution, intermittent or bolus delivery modes in critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the pump can be monitored or supervised by a clinician.

The Syringe Infusion Pump is not intended for use on the inlet side of extracorporeal membrane oxygenation (ECMO) systems where high negative pressures may occur.

The Medex 3000 Series MRI Syringe Infusion Pump is acceptable for use inside the MRI room mounted outside the 150 Gauss line and with shielded magnets of field strength of 1.5 Tesla or less.

807.92 (a) (6) Technical Characteristics Summary

The Medex 3000 Series MRI Syringe Infusion Pump is identical to the Medex 3000 Series Syringe Infusion Pump currently on the market under K982640.

807.92 (b) (1), (b) (3) Performance Testing Assessment

Medex completed testing to support the modifications to the device marketing claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

Ms. Cathy Chenetski
Director, Regulatory Affairs
Medex, Incorporated
6250 Shier-Rings Road
Dublin, Ohio 43016-1295

Re: K000328
Trade Name: Medex 3000 Series MRI Compatible Syringe Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 13, 2000
Received: April 18, 2000

Dear Ms. Chenetski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) _____

Device Name: Medex 3000 Series MRI Syringe Infusion Pump

Indications for Use:

The Medex 3000 Series MRI Syringe Infusion Pump indications for use are as follows:

- in the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics and other therapeutic fluids.
- in the following delivery routes: arterial, epidural, intravenous, spinal, and subcutaneous.
- in the following delivery modes: continuous, volume/time, mass, body weight, custom dilution, intermittent and bolus.
- in critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the Syringe Infusion Pump can be monitored or supervised by a clinician.
- the Syringe Infusion Pump is *contraindicated* for use on the inlet side of extracorporeal membrane oxygenation (ECMO) systems where high negative pressures may occur.
- inside the MRI room mounted outside the 150 Gauss line and with shielded magnets of field strength of 1.5 Tesla or less

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucento
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000328